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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee
Serial No: 10/019,570
Filed: 11-8-2001
For: Multiple Analyte Assay Device
Group Art Unit:1743 Examiner: L.A. Alexander

Reply Brief under 37 CFR 41.41(a)(1)

Appellant files this reply brief in response to the Examiner's Answer dated 01/09/2006. The Examiner's Answer raises a new issue, which is addressed in this reply brief. Appellant requests that the appeal be maintained.

(i) Real party

The real party in interest is the named inventor, Jin Po Lee.

(ii) Related appeals and interferences

There are no related appeals and interferences.

(iii) Status of the Claims

As set forth in the attached sheets, which separately show the status of all claims and the appealed claims. Claims 10 to 17 and 19 were finally rejected and are appealed. Claims 1-8 and 18 were finally rejected and are not appealed and Claims 8 and 20 to 25 have been withdrawn.

(iv) Status of the Amendments,

Typographical errors have been corrected in an amendment following final rejection, which was entered by the examiner. A terminal disclaimer, which had been submitted with the amendment, was initially accepted and entered but has now been rejected in the Examiner's Answer thus creating an additional issue.

(v)Summary of claimed subject matter.

The claimed subject matter defines a biological assay device for simultaneously, but separately, analyzing for multiple analytes in a fluid sample. The device comprises (page 9, lines 2-12, Figure 1[1] a generally flat housing base (**101**) containing a number of parallel slots (**102**), each separated by a wall or rail allowing (**103**) different test strips to be placed between the walls in the slots. The test strips (**105**) contain different binders, antibodies and labels to allow for the visual testing of different analytes (page 9, lines 18-22, Figure 1, **112**, **113**). The strips extend beyond

[1] Page numbers and drawing numbers refer to PCT application US98/15469

the housing so as to allow contact of a sample with the strips (page 9, lines 13-22, Figure 2, **102**). To protect the integrity of each assay test the housing is equipped with a cover (page 11, lines 5-14, Figure 1, **110,111, 115**), but containing windows (**111**) to allow for the viewing of the results in the test and control zones of the analytical assay strip (**112, 113**) inserted in the housing. In addition the device contains a removable cover or cap (page 12, lines 2-19 Figure 1, **220**, Figures 3A, 3B and 3C), which encloses the protruding ends of the test strips and provides an opening (**221**) for the fluid sample to be added to a reservoir (**222**) in the base of the cover housing (**223**) into which the individual strips are dipped. Thus, the device can also be employed without the cover by dipping the exposed assay strips directly into the fluid sample.

The key feature of the claimed invention is that it minimizes any cross contamination of the various assay strips. With the cap on, the exposed strips are protected during transport and any contact between the operator of the test and the sample is further reduced.

(vi) Grounds of Rejection to be Reviewed on Appeal

(1) The appealed claims have been rejected on the basis of obviousness double patenting over claims 1-19 of U.S. Patent No. 6,514,769 (the '769 patent).

(2). The appealed claims have been rejected as under 35 USC 102 (e) as being clearly anticipated by Kimrov et al US Patent No. 5,976,895 (Kimrov). The Examiner argues that Kimrov discloses an assay device comprising a plastic holder that will hold three to five membranes each capable of analyzing for a different drug of abuse. The membranes or assay strips of the reference contain each a detection site and a control site.

(vii) Argument

(A) The obviousness- double patenting rejection

The Examiner has raised this issue in his Answer after appellant had filed a terminal disclaimer, which had been accepted, on the basis of a typographical error. Appellant however, was not provided with an opportunity to correct such without

abandoning the appeal. Since the terminal disclaimer was filed in the hope of securing an allowance, which was not granted, appellant traverses the rejection.

Claims 1 to 19 of the '769 patent, issued to the same inventor and derived from the same parent application here on appeal, define an assay device which although containing similar elements as the assay device defined by the appealed claims, contains critical elements not contained in the appealed claims. At the same time the assay device of the appealed claims contains critical elements not contained in the claims of the '769 patent. The claims of each patent are deemed to be mutually exclusive. The claims of the '769 patent all contain a limitation to the use of a sample integrity monitoring system (See claim 1 section (C)) involving a separate second assay strip for each analyte tested. This is the inventive feature of the claims and is set forth in all of the claims. The claims here on appeal do not define a sample integrity monitoring system. Nothing in the appealed claims would suggest such. The claims of the '769 patent are therefore patentably distinct from the appealed claims. The appealed claims on the other hand define a removable cap on the exposed assay strips that allows the claimed device to be used as a cassette, by providing an opening and a reservoir for the sample to contact the assay strip in the cap (Figures 3A, 3B, 3C). No such cap is disclosed in the claims of the '769 patent. Again therefore the appealed claims are patentably distinct from claims 1-19 of the '769 patent.

In view of the absence of claim elements of the appealed claims contained in the claims of the '769 patent and the absence of claim elements in the '769 patent contained in the appealed claims, the claims are patentably distinct and the double patenting rejection is without basis and should be reversed.

(B) Anticipation under 35 U.S.C. 102 (e)

Appellant's appealed claims have been rejected as anticipated under 35 USC 102 (e). In order to constitute anticipation each and every element set forth in the claim must be found expressly or inherently described in a single prior art reference (See MPEP Section 2131). Appellant maintains that Kimrov fails to disclose several of the elements set forth in the appealed claims. In its main brief appellant argued that the reference fails to disclose critical elements of the appealed claims. Thus Kimrov fails to disclose (1) the exposed assay strips extending beyond the housing

and (2) the cap containing sample port and a reservoir below the sample port into which the assay strips are dipped allowing the device to be used both as a dipstick and as a cassette. .

The examiner argues that the sample pad **(109)** of Kimrov extends beyond the cover **(115)** and thus implies that the assay strips extend beyond the housing, i.e. beyond both the base and the cover as clearly shown in appellant's specification as Figure 2.

The examiner's reasoning is faulty. Thus the examiner has taken one element from one drawing and attempted to apply it to another. Thus the examiner ignores the fact that cover **(115)** is contained in Figure 1C, classified as prior art, and does not show sample pad **(109)**, whereas the Figure 1B showing the sample pad **(109)** does not contain the cover element **(115)** of Figure 1C. Figure 1B however does show that the sample pad **(109)**, which is in contact with the assay strip **(104)**, is enclosed by the wall of the holder **(102)** and the rubber seal. **(110)**. The only access to the sample pad is through a small borehole in the assay strip holder **(102)**. The examiner also referred to US Patent No. 5,403,551 (hereafter the '551 patent), incorporated into Kimrov by reference, as showing certain elements of the appealed claim. As can be seen there from Figure 3, 4 and 5 of the '551 patent, the sample pad **(52)**, as well as the assay strip **(46)**, is totally enclosed by the sample holder **(30)** and the backing plate **(48)**, leaving only a small borehole **(36)** for the sample to contact the sample pad **(52)**. Lacking the feature of a protruding assay dipstick, which enables the device of the appealed claims to be used as a dipstick, Kimrov fails as anticipation.

The Examiner's Answer further fails to address the particular design of the cap as defined in the appealed claims, which allows appellant's assay device to be used both as a cassette as well as a dipstick. Although Kimrov discloses a cap more specifically identified in the drawings of the '551 patent as **(28)**, it is a solid cap on the cup **(12)** that does not have a sample port in which the sample is applied to the assay strips. Nor does the cover of Kimrov disclose a reservoir beneath the sample port. The cap disclosed in Kimrov has be solid to prevent sample from escaping the device, since it has to be turned upside down in order for the sample to flow into the assay strip holder, totally contained within the cup. Thus not only do the assay strips not protrude beyond the strip holder but they further do not protrude beyond the cup requiring a cap for the protection of such.

Conclusion

It is submitted that Appellant has demonstrated that the appealed claims are patentably distinct from the claims of the '769 patent in that the appealed claims contain an element not in any way suggested by the '769 patent and that the claims of the '769 patent contain an element not suggested by the appealed claims. The double patenting rejection should therefore be vacated. It is further submitted that the Kimrov reference cited as anticipatory fails to disclose two of the elements of the claimed assay device and therefore fails to constitute an anticipation of the claims. There being no other grounds for rejection of the appealed claims a reversal of the final rejection and an allowance of the appealed claims is therefore requested.

Respectfully submitted,

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Certificate under 37 CFR 1.8

I hereby certify that foregoing reply brief and attachments were deposited with the United States Postal Service addressed Mail Stop: Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, by Priority Mail as of the date set forth below.

Bernd W. Sandt

Date 1/30/06

Evidence Appendix

1. US. Patent No. 5,770,458 (Kimrov) cited by Examiner in Final Office Action dated 11-26-2005.

2. US Patent No. 5,403,551 (Galloway et al) cited in the Examiner's Answer as part of the Kimrov patent. The patent is of record in the prosecution file.

3. US Patent No. 6,514,769 cited in the Examiner's Answer. The patent is of record in the prosecution file.

Related Proceedings Documents Appendix

There are no decisions rendered by a Court or the Board in any related proceedings.

Claims on Appeal

10. A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific fro a different analyte;

(C) a cover having (a) a first section attached to the upwardmost surface of each raised wall of the slots of the base, wherein the first section of the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and (b) a second section enclosing the protruding ends of the test strips, the second section comprising:

(i) a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test stripes;

(ii) a floor opposing the sample port, the floor comprising a wall having a raised bar therein which defines a fluid reservoir beneath the sample port.

11. (Original, finally rejected, appealed) The device according to claim 10 wherein the second section of the cover is removable from the first section of the cover.

12. The -device according to Claim 10 further comprising a second transparent

window formed within the cover through which the test strips can be viewed.

13. The device according to Claim 10 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

14. The device according to Claim 13 wherein each binder is specific for a different drug of abuse.

15. (Original finally rejected, appealed) The device according to Claim 13 wherein each test zone is visible through the first transparent window of the cover.

16. The device according claim13 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

17. The device according to claim 12 , wherein the label on the test strip is visible through the second transparent window of the cover.

19. The device according to Claim 13 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

Status of all Claims

1. (Twice amended, finally rejected, not appealed) A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte;

(C) a cover attached to the upwardmost surface of each raised wall of the slots of the base wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed.

2. (Original, finally rejected, not appealed) The device according to Claim 1 further comprising a cap for insertion over the protruding ends of the test strips.

3. (Original finally rejected, not appealed) The device according to Claim 1 further comprising a second transparent window formed within the cover through which the strips can be viewed.

4. (Original finally rejected, not appealed) The device according to Claim 1 wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

5. (Original finally rejected, not appealed) The device according to Claim 4 wherein each binder is specific for a different drug of abuse.

6. (Original finally rejected, not appealed) The device according to Claim4 wherein each test zone is visible through the first transparent window of the cover.

7. (Original finally rejected, not appealed) The device according to Claim 4 wherein each test strip further comprises a label upstream of the of the test zone, which label identifies the analyte for which the binder is specific.

8 (Twice amended finally rejected, not appealed) The device according to Claim 3, wherein the label on the test strip is visible through the second transparent window.

9. (Withdrawn)

10. (Once previously amended, finally rejected, appealed) A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific fro a different analyte;

(C) a cover having (a) a first section attached to the upwardmost surface of each raised wall of the slots of the base, wherein the first section of the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and (b) a second section enclosing the protruding ends of the test strips, the second section comprising:

(i) a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test stripes;

(ii) a floor opposing the sample port, the floor comprising a wall having a raised

bar therein which defines a fluid reservoir beneath the sample port.

11. (Original, finally rejected, appealed) The device according to claim 10 wherein the second section of the cover is removable from the first section of the cover.

12. (Original, finally rejected, appealed) The device according to Claim 10 further comprising a second transparent window formed within the cover through which the test strips can be viewed.

13. (Original, finally rejected, appealed) The device according to Claim 10 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

14. (Original, finally rejected, appealed) The device according to Claim 13 wherein each binder is specific for a different drug of abuse.

15. (Original finally rejected, appealed) The device according to Claim 13 wherein each test zone is visible through the first transparent window of the cover.

16. (Original, finally rejected, appealed) The device according claim13 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

17. (Twice Amended, finally rejected, appealed) The device according to claim 12 , wherein the label on the test strip is visible through the second transparent window of the cover.

18. (Original, finally rejected, not appealed) The device according to Claim 5 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and

benzodaizepine.

19. (Original, finally rejected, appealed) The device according to Claim 13 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

20. (Withdrawn)

21. (Withdrawn)

22. (Withdrawn)

23. (Withdrawn)

24. (Withdrawn)

25. (Withdrawn)